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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/789,548	02/26/2004	Donald W. Landry	30000.2USU1	9484

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EXAMINER

CHISM, BILLY D

ART UNIT PAPER NUMBER

1654

DATE MAILED: 01/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/789,548

Applicant(s)

LANDRY ET AL.

Examiner

B. Dell Chism

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1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-13 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Withdrawal of Objections and Rejections

The rejections and/or objections made in the prior office action mailed 22 April 2005, which are not explicitly stated below, in original or modified form are withdrawn.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Applicants' arguments filed 31 October 2005 will be addressed to the extent that they pertain to the present grounds of rejection.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. (Maintained) Rejection of Claims 1-4, 6 and 13 under 35 U.S.C. 102(b) as being anticipated by Lindberg et al. (Kidney International, 1988, Vol. 33, No. 1, page 229) (cited in previous office action) is maintained. The instant claim is to a method of reducing excess extracellular fluid in a patient undergoing hemodialysis by administration of a vasopressin receptor agonist and maintaining blood pressure during hemodialysis. Lindberg et al. teaches the administration of lysine vasopressin (LV) to patients undergoing hemodialysis and suffering from hemodialysis-induced hypotension. In contrast to Applicants' arguments, the methods definitively showed reduced hypotensive episodes during dialysis, and these patients required a statistically significant less amount of intravenous fluid administration; thus, Lindberg et al.

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teach using LV to treat refractory hemodialysis-induced hypotension through reduced hypotensive episodes and management of extracellular fluid due to reduced requirement of intravenous fluids.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. (New) Claims 1-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lindberg et al. (cited above) in combination with Dagher et al. (Aliment Pharmacol. Ther., 2000, Vol. 14, pages 515-521) and WO 88/01163. Lindberg et al. teach the use of the vasopressin receptor agonists, lysine vasopressin (LV), in treatment of refractory hemodialysis-induced hypotension for patients undergoing hemodialysis. The treatment in Lindberg et al. teaches a reduced rate of hypotensive episodes and reduced need for intravenous fluids during hemodialysis. However, Lindberg et al. do not teach arginine vasopressin, terlipressin, octapressin or ornipressin in the treatment methods.

Dagher et al. teach octapressin (a LV analogue), ornipressin and terlipressin, as substitutable components in treatment of hepatorenal syndrome in cirrhotic patients. However, Dagher et al. do not teach treatment of refractory hemodialysis-induced hypotension or the reduction of excess extracellular fluid.

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WO 88/01163 teaches LV, arginine-vasopressin and ornipressin as alternate yet functionally equivalent substitutes; however, WO 88/01163 does not teach treatment of refractory hemodialysis-induced hypotension or the reduction of excess extracellular fluid.

One of ordinary skill within the art would be motivated to use LV, arginine-vasopressin, octapressin (a LV analogue), ornipressin and terlipressin in the treatment of refractory hemodialysis-induced hypotension or the reduction of excess extracellular fluid as taught by Lindberg et al. As demonstrated by Dagher et al. and WO 88/01163, arginine-vasopressin, octapressin (a LV analogue), ornipressin and terlipressin are art recognized alternate yet functionally equivalent compounds to LV that are substitutable for each other, and one of ordinary skill in the art would have an expectation of success because LV, an art recognized alternate yet functional equivalent to arginine-vasopressin, octapressin (a LV analogue), ornipressin and terlipressin, is taught by Lindberg et al. to be biologically active to achieve the instantly claimed methods. Therefore, it would have been obvious to one of ordinary skill in the art to combine or substitute the instantly claimed compounds to achieve the instantly claimed methods and to do so with the expectation of success.

Conclusion

5. No claims are allowed.
6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to B. Dell Chism, whose telephone number is (571) 272-0962. The examiner can normally be reached on M-F 08:30 AM - 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, PhD can be reached on (571) 272-0974.

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The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

BDC


B. DELL CHISM
PATENT EXAMINER